

**REMARKS**

In the Official Action of August 23, 2007 the Examiner raised a number of objections with respect to the drawings, specification and claims, and also rejected many of the claims on the cited references, but many other claims were indicated as allowable. A number of amendments have been made to the specification and claims which, it is believed, avoid the technical objections raised by the Examiner and also more clearly distinguish the claims over the cited references. Favorable reconsideration of the application is respectfully requested in the light of these amendments, and the following remarks.

**Re the Drawings**

The drawings were objected to on the grounds that “the adhesive layer on the surface of the base facing the pressure applicator and sensor claimed in Claim 11 must be shown or the feature(s) cancelled from the claim(s)”. It is submitted, however, that this feature is now clearly shown in the drawings, and therefore no drawing corrections are needed.

For example, we refer to the paragraph of Page 10, lines 912–15, particularly the following passage:

“The surface of base 11 facing the pressure applicator 12 and sensor 13, brought into contact with the subject’s skin, includes an adhesive layer 14 for adhering the base to the subject’s skin at the measurement site.”

The adhesive layer is clearly seen at 14 in Figs. 1b, 1c, and at 24, 34, 44, 54 and 84 in many of the other figures of the drawings, and it is submitted that the above-quoted passage describing Figs. 1b, 1c, and the corresponding pages describing 24, 34, 44, 54, 84 clearly support the language used in Claim 11, and therefore no drawing correction is necessary.

**Objections to the Specification**

The first objection, based on Claim 11, is believed answered by the above discussion with respect to the drawings.

With respect to the objections regarding the language used in Claims 35, 36 and 38, these claims have been amended to conform the language therein to that used in the specification, thereby avoiding this objection.

With respect to the objection regarding the language used in Claim 49, it is believed that the language used in that claim is fully supported in the passage starting on Page 10, line 24, through Page 11, line 5, which clearly brings out that the pressure applicator (12) is itself part of the pneumatic system. The informalities raised with respect to Claims 47 and 49 have been corrected in the amended claims.

**The Rejection based on the Kan Publication**

In this rejection, the Examiner feels that this publication shows a pressure applicator which is applied to a restricted part of the wrist's circumference.

However, it is to be noted that the pressure applicator in the Kan publication is mounted on a base (5) which, together with a wrist holding bracket (6), to which the base's free ends are fixed, completely encompasses the wrist.

It is to be first noted that the device described in the Kan publication relates to the "oscillometric" method of measuring blood pressure in which the pressure applied is not a "static" pressure, but rather is a periodically-varying pressure. Since Claim 1 clearly recites "applying a static pressure", it is believed that this is sufficient to distinguish Claim 1 from the disclosure in that patent publication.

However, more importantly, Claim 1, as amended, sets forth that the probe is configured to be applied to a relatively restricted area of the subject's skin, to apply the static pressure to the relatively restricted area, which area does not completely

encircle the body part at the measurement site, and that the pressure applicator occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site, to thereby permit free venous draining from the measurement site via a wide region of unrestricted passageways surrounding the measurement site. This can be readily seen from the figures of the current application, in which the absence of a complete encircling of the body part by the probe is clearly obvious.

Such a construction and mode of operation is not present in the Kan publication since the supporting base described in that publication completely encompasses the circumference of the body region under some tension sufficient to induce venous distention.

For example, U.S. Patent 5,540,714, shows that the mere encircling of a body region tightly with an elastic strap is sufficient to induce venous distention. Accordingly, since merely applying a supporting band which completely encompasses the circumference of a body region under some tension can be sufficient to induce venous distention, it is clear that further applying a pressure applicator under such a supporting base, as described in the Kan publication, will also generate a pressure field throughout the entire tissue mass. This, for example, is apparent from the commonly used blood pressure cuff in which the inflatable bladder does not completely encircle the arm, yet complete occlusion of blood flow can be achieved when it is adequately pressurized.

This distinction over the Kan publication is further apparent by the following passage in paragraph 47 of that publication:

“In addition, the strap 5 should possess appreciable elasticity so that when the diameter of the wrist is reduced due to long-term, continuous pressure, its resilient capability can still enable the bladder 3 to wrap tightly onto the wrist without any movement.”

For the foregoing reasons, it is submitted that Claim 1, particularly as now amended, is not disclosed in or rendered obvious from the Kan publication.

Since all the other claims depend from Claim 1, it is submitted that these claims are also allowable over that patent.

### **The Rejection under 35 U.S.C. 103**

Claim 1, and other claims, were rejected under 35 U.S.C. 103 as unpatentable over Bobo et al in view of Sasaki et al.

Bobo et al, relied upon as the primary reference in this rejection, also relates to blood pressure measurements by the oscillometry technique, in which the pressure is a varying one, rather than a static one. Since Claim 1 recites a “static pressure”, it is believed that this is sufficient to distinguish Claim 1 over this reference, whether taken alone or in combination with the secondary reference.

However, and more importantly, it is to be noted that in the Bobo et al design, the inflatable bladder is fixed on the surface of the pad facing the patient and extends out from the pad and backing, as clearly stated by Bobo et al in the description of Fig. 1. This means that the bladder 18 and bladder backing 19 would be interposed between the adhesive pad 20 and the body surface, and would generate a local pressure at the tissue interface with elements 18 and 19 after the backing 20 was adhered to the patient’s skin.

Such a design would result in there being a force applied to the body surface at the site at which the probe is adhered to the patient even without the pressure bladder being pressurized since “the bladder extends out from the pad and back”, and therefore when the pad 20 is adhered to the skin, the bladder 18, and bladder backing 19, must be forced to press on the body surface. Since the actual magnitude of such a force could not be known in advance, it would certainly not be possible to ensure that

the pressure would impart “a static pressure of a sufficient magnitude to partially unload the wall tension of, but not to occlude, the arteries — — —”, as defined in Claim 1.

In other words, forcing the elements 18 and 19 against the skin when element 20 is adhered to the skin would preclude being able to determine the actual pressure being applied, and thus prevent an accurate pressure measurement from being made.

In contrast to the design of the Bobo device, in the device of the present invention the fluid chamber 15 is not designed to extend beyond the surface of the patient oriented side of base 11, and would therefore not exert a pressure at the measurement site when the base 11 is adhered to the patient’s body surface. An appropriate static pressure would thus only be generated when the pressure applicator 12 is pressurized to a desired level in order to apply “a static pressure of a sufficient magnitude to partially unload the wall tension of, but not to occlude, the arteries — — —”, as defined in Claim 1.

The above described structural differences between the device of the present application and the Bobo patent can be further understood by comparing Figs. 1a–1c of the present application with the Figs. 1 and 2 of the Bobo patent.

It is submitted, therefore, since Bobo does not qualify as a proper primary reference, its combination with the secondary reference would not render the device of the present invention obvious.

Claim 1 was also rejected under 35 U.S.C. 103 as being unpatentable over Oka et al, U.S. Patent 5,743,856 in view of Kan. However, since Kan is not relevant to the invention of the present application, it is submitted that this combination also does not provide an anticipation of Claim 1.

With respect to the rejection of some claims over Kan in view of other secondary references, it is submitted that, for the reasons discussed above, Kan does not qualify as a proper primary reference with respect to the subject matter defined in these claims, and therefore its combination with the secondary references would not provide an anticipation of the invention defined in those claims.

For the foregoing reasons, it is submitted that Claim 1, particularly as now amended, is allowable over all the references cited by the Examiner. Since the remaining claims all depend from Claim 1, it is submitted that these claims are also allowable for the same reasons as set forth above with respect to Claim 1, apart from the further features set forth in the respective dependent claims.

The specification has been amended merely to provide clear antecedent terminology for the language used in the claims, and to overcome the minor technical objections raised by the Examiner.

In view of the foregoing, it is believed this application is now in condition for allowance, and an early Notice of Allowance is respectfully requested.

Respectfully submitted



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**Enclosures:**

- Petition for Extension (one Month)